

**Remarks:**

Reconsideration of the present application is respectfully requested. Claims 60-72 remain in this application with claims 60, 68, 69, and 71 being in independent format. In view of the claims as they now stand, together with the remarks hereunder, the rejections of the Office Action dated July 28, 2005 must be respectfully traversed.

Claim 39 was objected to for an informality. This claim was canceled in the previous office action response and therefore was not pending for this action. Accordingly, Applicant respectfully requests that this objection be removed.

Claims 60-72 were rejected under 35 U.S.C. 112, second paragraph for being indefinite. Section (A) of this rejection has been overcome by amending "the cancer" to "said cancer" in order to provide antecedent basis for the claims. Section (B) of this rejection has been overcome by removing "corresponding to" and "an amino acid sequence of" from the claims. Each of the claims now recites that the HLA-F antigen comprises a specific SEQ ID No., or is expressed by a specific SEQ ID No. Such terminology is well accepted and Applicant asserts that these rejections have been overcome. Section (C) of this rejection again referred to claims that had been canceled in the last response and therefore, were not pending for this action. Accordingly, this section of the rejection should be withdrawn.

Claims 60-72 were also rejected under 35 U.S.C. 112, first paragraph for having inadequate written description or new matter. Specifically, the definition of the HLA-F antigen was alleged to lack structural constraints. Applicants assert that this rejection has been overcome by amending specific SEQ ID Nos. into the claims in order to better define the claimed HLA-F antigen. With respect to the new matter rejection, claim 68 referred to a 25KDa antigen. Support for the claimed

25 Kda antigen is provided in Example 3, on page 21, as noted in the response to the last office action. Accordingly, Applicant asserts that this rejection should be withdrawn.

Claims 60-64 and 68-72 were rejected under 35 U.S.C. 102(b) over WO99/53938 to Stockert et al (Stockert). In the action, it was noted that the 112 issues addressed above contributed to this rejection. These rejections have been addressed in a manner that overcomes the 112 issues, as well as the alleged 102(b) issues. Stockert does not disclose any of the claimed SEQ ID Nos. and for that reason alone, cannot be said to anticipate the present claims as each are limited to a specific SEQ ID No. Additionally, Stockert does not disclose an HLA-F antigen comprising the claimed SEQ ID Nos. Applicant would like to note that a portion of this rejection included an indication that these claims were product by process claims. This is simply not true. A product by process claim is a claim for a product made by a specific process. All of the claims of this application are clearly method claims and not product claims. Thus, any rejections based on MPEP rules regarding product by process claims are misplaced. Accordingly, Applicant asserts that this rejection has been overcome.

Claims 60-62, 64-67, and 69-72 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,094,942 to Hashizume et al (Hashizume). Similar to the 102(b) rejection over Stockert, Hashizume does not disclose or suggest the claimed SEQ ID Nos, nor does Hashizume disclose or suggest an HLA-F antigen comprising the claimed SEQ ID Nos. Accordingly, Applicant asserts that this rejection has been overcome by the amendment herein.

Claims 60-67 and 69-72 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hashizume in view of the Sigma catalog (the catalog). This rejection is based on the allegation that the carboxypeptidase of Hashizume can be replaced with the HLA-F antigen and then use goat or

mouse or human from the catalog. Neither of these references teach or suggest a HLA-F antigen, especially one as claimed herein as comprising a specific sequence or being expressed by a specific sequence. Additionally, neither reference teaches or suggests the very basis upon which this invention is based, that a healthy individual does not have anti-HLA-F in their body fluid, while an individual having a cancer that is non-specific to various organs does have anti-HLA-F in their body fluid. Because neither reference teaches or suggests anti-HLA-F antibody, it could not be obvious that a cancer non-specific to various organs could have been diagnosed using the claimed methods herein without the use of the present disclosure as a blueprint or guide. Such a hindsight piecing together of prior art is not permitted. Applicants further note that Table 4 of Hashizume shows that the method therein could result in a positive reaction, even in individuals that do not have a cancer non-specific to various organs. The one instance of what was thought to be a false positive using the methods of the present invention turned out to be a sample from a patient thought to be healthy, but upon further examination, it was discovered that they had colon cancer. Such a finding further underlies the accuracy of the presently claimed methods. Two references, enclosed herein, further teach those of skill in the art away from the present invention. Both Human Immunology 29, 131-142 (1990) and the Journal of Immunology 171, 5264-5271 (2003) concluded that HLA-f antigen was expressed in healthy subjects. Accordingly, those of skill in the art would have been discouraged to use the methods claimed herein. Such evidence further emphasizes the non-obvious nature of the present claims. Accordingly, Applicant asserts that this rejection has been overcome.


In view of the amendments and remarks herein, a Notice of Allowance appears to be in order and such is courteously solicited herein.

Any additional fee which is due in connection with this amendment should be applied against

our Deposit Account No. 19-0522.

Respectfully submitted,

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